12. SUMMARY OF SAFETY AND EFFECTIVENESS:
Submission in accordance with the requirements of 21 CFR Part 807.87(h)

1) Submitter:	MEDIS *medical imaging systems* B.V.
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Contact Person:	J.I. Hollander, Quality Coordinator
Prepared:	November 25, 2002
2) Device Name:	QVA-CMS analytical software package
Common Name:	QVA-CMS
Device Class. Name:	System, X-ray, Angiographic
Regulation Number:	21 CFR 892.1600 (90 IZI; Class II)
3) Predicate Device:	QCA-CMS; 510(k) K993763

4) Device Description:
QVA-CMS is a state-of-the-art analytical software tool designed for Windows operating systems. QVA-CMS analytical software facilitates the import and visualization of X-ray images via CD-ROM and digital network. The QVA-CMS functionality is independent of the X-ray acquisition equipment vendor. QVA-CMS, performing automated contour detection, provides quantitative analysis with objective and reproducible assessment of vascular lesions in selected regions of interest. The analysis results of user's selection can be reported in user-defined configuration, exported in general formats and transported for storage via communication with standard Microsoft office packages.

5) Intended use:
The analytical QVA-CMS software, serves a medical purpose and its intended use is:

a) To quantify medical images of peripheral arteries in an objective and reproducible way by presenting graphs with calculated data of user's selected regions of interest. Quantification is performed by automated contour detection;
b) To improve the interpretation of vascular images for decisions by the clinicians in hospitals, facilitated by image quantification;
c) To improve the analysis of the vascular morphology during research trials by analysts in Core Labs on intervention effects, facilitated by image quantification;
d) To train users for correct interpretation and analysis of images of peripheral arteries, using the objective and reproducible quantified images;
e) To reduce the risks, due to user variability associated with conventional visual assessment, facilitated by objective and reproducible quantified images;
f) To gain more benefits in post-processing activities, avoiding the very time-consuming conventional manual tracing of boundaries, using the automated contour detection of the analytical software package.

6) Substantial equivalence Information:
The QVA-CMS software is substantially equivalent to the predicate device of QCA-CMS, K993763, using the same technological characteristics and intended use.

CONCLUSIONS RESPECTING SAFETY and EFFECTIVENESS:

It is the opinion of MEDIS *medical imaging systems* B.V. that QVA-CMS is safe and potential hazards are controlled by the risk management plan for the software development process (see Appendix C), including hazard analysis (see Appendix D), verification and validation tests (see Appendix E). Evaluation by hospitals and literature (see Appendix F) supports this statement.
In MEDIS' opinion the level of concern for the stand-alone software to quantify images is 'minor' and that the use of QVA-CMS analytical software does not influence the use of X-ray image acquisition equipment in practice, nor does the use of software result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2003

Mr. J. I. Hollander
Quality Coordinator
MEDIS Medical Imaging Systems, B. V.
Poortgebouw, Rijnsburgerweg 10
2333 AA Leiden
NETHERLANDS

Re: K023970
Trade/Device Name: Quantitative Vascular Angiography - CMS
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: 90 IZI
Dated: November 25, 2002
Received: November 29, 2002

Dear Mr. Hollander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023970

Device Name: Quantitative Vascular Angiography - CMS

Indications For Use: QVA-CMS is developed for the quantitative analysis of vascular morphology in peripheral arteries and is applicable in both research studies and during interventions in the vascular lab. The automated contour detection can be used to standard digital, subtracted and inverted images. The package reduces significantly the intra- and inter-observer variability associated with conventional visual assessment. It also avoids the very time-consuming conventional manual tracing of boundaries. QVA-CMS analytical software is intended to support clinicians, i.e. cardiologists, radiologists, and referring physicians involved in the assessment of X-ray images. When interpreted by trained physicians these parameters may be useful in supporting a clinical decision process.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023970